



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 26, 2015

OMNIIlife Science, Inc.
Ms. Vani Sindwani
Regulatory Affairs Specialist
50 O'Connell Way, Suite 10
East Taunton, Massachusetts 02718

Re: K142201

Trade/Device Name: OMNI Interface™ Acetabular System

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH, LZO, MEH

Dated: November 25, 2014

Received: November 28, 2014

Dear Ms. Sindwani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 **Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K142201

Device Name: OMNI (previously Apex) Interface™ Acetabular System

Indications for Use:

The OMNI Interface™ Acetabular System is designed to be used in hip arthroplasty. The specific indications for use include -

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

The OMNI Interface Acetabular System is intended for cementless and single use implantation only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary**TABLE 1: 510(k) SUMMARY**

<i>Date Summary Prepared</i>	08/08/2014
<i>Manufacturer/Distributor/Sponsor</i>	OMNIlife Science, Inc. 50 O'Connell Way Suite 10 East Taunton, MA 02718
<i>510(k) Contact</i>	Vani Sindwani Regulatory Affairs Specialist OMNIlife Science 50 O' Connell Way Suite 10 East Taunton, MA 02718 Telephone: 774-226-1871 Fax: 508-822-6030 Email: vsindwani@omnils.com
<i>Trade Name</i>	OMNI Interface™ Acetabular System
<i>Common Name</i>	Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
<i>Classification</i>	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. LPH
<i>Predicate Device</i>	K112779 Apex Interface Acetabular System K060635 Consensus Acetabular Shell System K123782 Paragon Hip System <u>Reference Predicates:</u> K031110 Apex Acetabular Shell
<i>Purpose of Submission</i>	This traditional 510(k) premarket notification is being submitted to expand the indications for OMNI Interface Acetabular System. Through this premarket notification OMNI intends to obtain clearance for the use of OMNI Interface Acetabular System with Global's Paragon stem cleared via K123782.
<i>Device Description and Intended Use</i>	The OMNI Interface Acetabular System consists of acetabular cups/shells that are made of titanium alloy, standard and crosslinked ultra high molecular weight polyethylene shell inserts and femoral heads that are used with compatible femoral hip stems for primary and

	<p>revision total hip replacement. The shells are available in “no hole” and “3-hole” configuration and a size range from 46-76 mm and X size (48x-58xmm).</p> <p>The OMNI Interface™ Acetabular System is designed to be used in hip arthroplasty. The specific indications for use include -</p> <ul style="list-style-type: none"> • Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; • Rheumatoid arthritis; • Correction of functional deformity; • Congenital dislocation; • Revision procedures where other treatments or devices have failed; • Femoral neck and trochanteric fractures of the proximal femur. <p>The OMNI Interface Acetabular System is intended for cementless and single use implantation only.</p>
<p><i>Substantial Equivalence Summary</i></p>	<p>The OMNI Interface Acetabular System is substantially equivalent to the predicates as the basic design, interface, fundamental technology, materials and intended use are the same.</p> <p>Paragon stem (K123782) is cleared to be used in conjunction with a compatible femoral head and acetabular component and is used with Consensus CS2 Acetabular Shell System (K060635). OMNIlife science has determined OMNI Interface Acetabular System to be substantially equivalent to CS2 Acetabular Shell System thereby supporting its use with the Paragon stem.</p> <p>The use of OMNI Interface Acetabular System with the Paragon stem is determined to be as safe and effective as the predicate and does not raise any new safety or effectiveness concerns. The results of testing for the proposed use of OMNI Interface Acetabular System with the Paragon Stem met the performance requirements for range of motion per ISO 21535.</p>

	<p>The comparison between OMNI hip stems and the Paragon stem, and OMNI and Global femoral heads have been included in this submission that further supports the compatibility of OMNI Interface Acetabular System and Paragon Stem.</p> <p>Based on the identical material, the design and characterization data, compatibility and mechanical testing, and technological characteristics, OMNIlife science believes the proposed OMNI Interface Acetabular System to be substantially equivalent to legally marketed predicates and can be used with Paragon stem for primary and revision hip arthroplasty.</p>
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